Application No. 10/688,786
Reply to Office Action of February 1, 2005

AMENDMENTS TO THE CLAIMS

This listing of claims replaces all prior versions and listings of claims in the application:

Listing of Claims:

1. (Original) A composition for the sustained release of biologically active polypeptide comprising: a biocompatible polymer having dispersed therein a biologically active polypeptide, a sugar and a salting-out salt.

2. (Original) The sustained release composition of Claim 1, wherein the polypeptide is selected from glucagon, glucagon-like peptides, exendins, agonists of glucagon like peptides, vasoactive intestinal peptide, immunoglobulins, antibodies, cytokines, interleukins, macrophage activating factors, interferons, erythropoietin, tumor necrosis factor, colony stimulating factors, insulin, enzymes, tumor suppressors, blood proteins, follicle stimulating hormone, growth hormone, adrenocorticotropic hormone, and luteinizing hormone releasing hormone, NGF, EGF, gastrin, GRH, defensin, enkephalins, and muteins, analogs, deletion and substitution variants and pharmaceutically acceptable salts thereof.

3. (Original) The sustained release composition of Claim 1, wherein the biologically active polypeptide is a glucoregulatory peptide.

4. (Original) The sustained release composition of Claim 3, wherein the glucoregulatory peptide is selected from GLP-1, GLP-2, exendin-3, exendin-4 or a combination thereof.

5. (Original) The sustained release composition of Claim 1, wherein the biologically active polypeptide is present from about 0.01% (w/w) to about 50% (w/w) of the total weight of the composition.

6. (Original) The sustained release composition of Claim 5, wherein the biologically active polypeptide is present in a range from about 0.1% (w/w) to about 30% (w/w) of the total weight of the composition.

7. (Original) The sustained release composition of Claim 6, wherein the polypeptide is present from about 0.1% (w/w) to about 10% (w/w) of the total weight of the sustained release composition.

8. (Original) The sustained release composition of Claim 7, wherein the polypeptide is present from about 0.5% (w/w) to about 5% (w/w) of the total weight of the sustained release composition.

9. (Original) The sustained release composition of Claim 1, wherein the sugar is present from about 0.01% to about 50% w/w of the total weight of the sustained release composition.

10. (Original) The sustained release composition of Claim 9, wherein the sugar is present from about 0.01% to about 10% w/w of the total weight of the sustained release composition.

11. (Currently Amended) The sustained release composition of Claim 10, wherein the sugar [[~~ins~~]] is present from about 0.1% to about 5% w/w of the total weight of the sustained release composition.

12. (Original) The sustained release composition of Claim 1, wherein the sugar is selected from a monosaccharide, a disaccharide, a sugar alcohol or a combination thereof.

13. (Original) The sustained release composition of Claim 12, wherein the sugar is selected from sucrose, trehalose, mannitol and combinations thereof.

14. (Original) The sustained release composition of Claim 12, wherein the sugar is a disaccharide.

15. (Original) The sustained release composition of Claim 14, wherein the disaccharide is sucrose, trehalose or a combination thereof.

16. (Original) The sustained release composition of Claim 1, wherein the salting-out salt comprises a salt containing a cation selected from Mg^{+2}, Li^{+}, Na^{+}, K^{+} and NH_4^{+} and combinations thereof.

17. (Original) The sustained release composition of Claim 1, wherein the salting-out salt comprises a salt containing an anion selected from SO_4^{-2}, HPO_4^{-2}, acetate, citrate, tartrate, Cl^{-}, NO_3^{-}, ClO_3^{-}, I^{-}, ClO_4^{-} and SCN^{-} and combinations thereof.

18. (Original) The sustained release composition of Claim 1, wherein the salting-out salt is ammonium sulfate.

19. (Original) The sustained release composition of Claim 1, wherein the salting-out salt is present from about 0.01% to about 50% w/w of the total weight of the sustained release composition.

20. (Original) The sustained release composition of Claim 19, wherein the salting-out salt is present from about 0.01% to about 10% w/w of the total weight of the sustained release composition.

21. (Original) The sustained release composition of Claim 1, wherein the biocompatible polymer is selected from the group consisting of poly(lactides), poly(glycolides), poly(lactide-co-glycolides), poly(lactic acid)s, poly(glycolic acid)s, poly(lactic acid-co-glycolic acid)s, polycaprolactone, polycarbonates,

polyesteramides, polyanhydrides, poly(amino acids), polyorthoesters, polycyanoacrylates, poly(p-dioxanone), poly(alkylene oxalate)s, biodegradable polyurethanes, blends thereof and copolymers thereof.

22. (Original) The sustained release composition of Claim 21, wherein said polymer comprises poly(lactide-co-glycolide).

23. (Original) The sustained release composition of Claim 1, further comprising a corticosteroid.

24. (Original) The sustained release composition of Claim 23, where the corticosteroid is selected from 21-Acetoxypregnenolone, Alclometasone, Algestone, Amcinonide, Beclomethasone, Betamethasone, Budesonide, Chloroprednisone, Clobetasol, Clobetasone, Clocortolone, Cloprednol, Corticosterone, Cortisone, Cortivazol, Deflazacort, Desonide, Desoximetasone, Dexamethasone, Disflorasone, Diflucortolone, Difluprednate, Enoxolone, Fluazacort, Flucloronide, Flumethasone, Flunisolide, Flucinolone Acetonide, Fluocinonide, Fluocortin Butyl, Flucortolone, Fluorometholone, Fluperolone Acetate, Fluprednidence Acetate, Fluprednisolone, Flurandrenolide, Fluticasone Propionate, Formocortal, Halcinonide, Halobetasol Propionate, Halometasone, Halopredone Acetate, Hydrocortamate, Hydrocortisone, Loteprednol Etabonate, Mazipredone, Medrysone, Meprednisone, Methylprednisolone, Mometasone Furoate, Paramethasone, Prednicarbate, Prednisolone, Prednisolone 25 – Diethylamino-acetate, Prednisolone Sodium Phosphate, Prednisone, Prednival, Prednylidene, Rimexolone, Tixocortol, Triamcinolone, Triamcinolone Acetonide, Triamcinolone Acetonide 21-oic acid methyl ester, Triamcinolone Benetonide, Triamcinolone Hexacetonide, Triamcinolone Diacetate, pharmaceutically acceptable mixtures and salts thereof.

25. (Original) The sustained release composition of Claim 24, wherein the corticosteroid is selected from Triamcinolone, Triamcinolone Acetonide, Triamcinolone Acetonide 21-oic acid methyl ester, Triamcinolone Benetonide, Triamcinolone Hexacetonide, Triamcinolone Diacetate, pharmaceutically acceptable mixtures and salts thereof.

26. (Original) The sustained release composition of Claim 23, wherein the corticosteroid is incorporated into the sustained release composition.

27. (Original) The sustained release composition of Claim 23, wherein the corticosteroid is separately incorporated into a second biocompatible polymer.

28. (Original) The sustained release composition of Claim 27, wherein the second biocompatible polymer is the same as the biocompatible polymer of the sustained release composition.

29. (Original) The sustained release composition of Claim 27, wherein the second biocompatible polymer is different from the biocompatible polymer of the sustained release composition.

30. (Original) The sustained release composition of Claim 23, wherein the corticosteroid unencapsulated but commingled with the sustained release composition.

31. (Original) A composition for the sustained release of biologically active polypeptide comprising: a biocompatible polymer having dispersed therein exendin-4, sucrose and ammonium sulfate.

32. (Original) The composition of Claim 31, wherein the biocompatible polymer is selected from poly(lactides), poly(glycolides), poly(lactide-co-glycolides),

poly(lactic acid)s, poly(glycolic acid)s, poly(lactic acid-co-glycolic acid)s and blends and copolymers thereof.

33. (Original) The composition of Claim 31, wherein the sucrose is present at a concentration from about 0.01% w/w to about 10% w/w of the total weight of the sustained release composition.

34. (Original) The composition of Claim 31, wherein the ammonium sulfate is present at a concentration of from about 0.01% w/w to about 10% w/w of the total weight of the sustained release composition.

35. (Original) The sustained release composition of Claim 31, wherein the exendin-4 is present at a concentration of about 0.1% to about 10% of the total weight of the composition.

36. (Withdrawn) A method of treating a patient suffering from Type 2 diabetes comprising administering a therapeutically effective amount of a sustained release composition comprising a biocompatible polymer having dispersed therein a biologically active exendin-4, a sugar and a salting-out salt.

37. (Withdrawn) The method of Claim 36, wherein the biocompatible polymer of the sustained release composition is selected from poly(lactides), poly(glycolides), poly(lactide-co-glycolides), poly(lactic acid)s, poly(glycolic acid)s, poly(lactic acid-co-glycolic acid)s and blends and copolymers thereof.

38. (Withdrawn) The method of Claim 36, wherein the sugar is present in the sustained release composition at a concentration from about 0.01% w/w to about 10% w/w of the total weight of the sustained release composition.

39. (Withdrawn) The method of Claim 36, wherein the salting-out salt in the sustained release composition is present at a concentration of from about 0.01% w/w to about 10% w/w of the total weight of the sustained release composition.

40. (Withdrawn) The method of Claim 36, wherein the exendin-4 is present in the sustained release composition at a concentration of about 0.1% to about 10% of the total weight of the composition.